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PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:  
Leland F. WILSON et al.

Serial No.: CIP of Serial No. 09/539,484

Group Art Unit: Unassigned

Filing Date: Concurrently herewith

Examiner: Unassigned

Title: AS-NEEDED ADMINISTRATION OF AN ANDROGENIC AGENT TO ENHANCE  
FEMALE SEXUAL DESIRE AND RESPONSIVENESS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

The references identified below and as listed as Reference Nos. AA-BC on attached Forms PTO-1449 were disclosed in parent application Serial No. 09/539,484, filed March 30, 2000, and, as such, copies thereof are not included with this statement pursuant to the provisions of 37 CFR § 1.98(d).

U.S. PATENT DOCUMENTS		
PATENT NO.	ISSUE DATE	PATENTEE
Serial No. 08/954,122	Filed 10/20/97	Neal
Serial No. 09/391,412	Filed 9/8/99	Neal
3,800,038	3/26/74	Rudel

U.S. PATENT DOCUMENTS		
PATENT NO.	ISSUE DATE	PATENTEE
3,948,254	4/6/76	Zaffaroni
3,967,618	7/6/76	Zaffaroni
4,014,987	3/29/77	Heller et al.
4,112,942	9/12/78	Scaife
4,128,577	12/5/78	Nelson
4,254,145	3/3/81	Birnbaum
4,454,339	6/12/84	Skuballa
4,507,323	3/26/85	Stern
4,521,421	6/4/85	Foreman
4,564,362	1/14/86	Burnhill
4,680,312	7/14/87	Johnson
4,818,517	4/4/89	Kwee et al.
4,961,931	10/9/90	Wong
4,976,692	12/11/90	Atad
5,190,967	3/2/93	Riley
5,565,466	3/15/96	Gioco et al.
5,698,589	12/16/97	Allen
5,731,339	3/24/98	Lowrey
5,773,020	6/30/98	Place
5,773,457	6/30/98	Nahoum
5,891,915	4/6/99	Wysor et al.
6,031,002	2/29/00	Wysor et al.

FOREIGN PATENT DOCUMENT		
DOCUMENT NO.	PUBLICATION DATE	COUNTRY
WO 99/20266	4/29/99	PCT

OTHER DOCUMENTS		
Frishman et al. (1992), "Evaluation of Astroglide, a New Vaginal Lubricant: Effects of Length of Exposure and Concentration on Sperm Motility," <i>Fertility and Sterility</i> <u>58</u> (3):630.		
Levin (1991), "VIP, Vagina, Clitoral and Periurethral Glans — An Update on Human Female Genital Arousal," <i>Exp. Clin. Endocrinol.</i> <u>98</u> (2):61-69.		
Semmens (1974), <i>Medical Aspects of Human Sexuality</i> <u>8</u> :85-86.		

The references identified below and listed as Reference Nos. BD-BR on attached Forms PTO-1449 are newly cited, and, as such, copies thereof are included with this statement.

U.S. PATENT DOCUMENTS		
PATENT NO.	ISSUE DATE	PATENTEE
4,147,783	4/3/79	van der Vies
4,150,128	4/17/79	Jasionowski
4,948,790	8/14/90	Archer et al.
5,622,944	4/22/97	Hale et al.
6,036,977	3/14/00	Drizen et al.
6,110,906	8/29/00	Labrie et al.

OTHER DOCUMENTS		
Bartlik et al. (1999), "The Combined Use of Sex Therapy and Testosterone Replacement Therapy for Women," <i>Psychiatric Annals</i> <u>29</u> (1):27-33.		
Berman et al. (1999), "Anatomy and Physiology of Female Sexual Function and Dysfunction," <i>European Urology</i> <u>38</u> :20-29.		
Davis (1999), "Androgen Treatment in Women," <i>The Medical Journal of Australia</i> <u>170</u> :545-549.		
Hutchinson (1995), "Androgens and Sexuality," <i>The American Journal of Medicine</i> <u>98</u> (Supp. 1A):111S-115S.		
Mathews et al. (1983), "Psychological and Hormonal Factors in the Treatment of Female Sexual Dysfunction," <i>Psychological Medicine</i> <u>13</u> :83-92.		
Shifren et al. (2000), "Transdermal Testosterone Treatment in Women with Impaired Sexual Function After Oophorectomy," <i>The New England Journal of Medicine</i> <u>343</u> (10):682-688.		

OTHER DOCUMENTS
Shifren et al. (2000), "Clinical Questions: Do Women with Impaired Sexual Function Following Oophorectomy Benefit from Transdermal Testosterone at a Physiologic Dose?," <i>The Journal of Family Practice</i> <u>49</u> (12):1148.
Tutten et al. (1996), "Discrepancies Between Genital Responses and Subjective Sexual Function During Testosterone Substitution in Women with Hypothalamic Amenorrhea," <i>Psychosomatic Medicine</i> <u>58</u> :234-241.
Warnock et al. (1999), "Female Hypoactive Sexual Disorder: Case Studies of Physiologic Androgen Replacement," <i>Journal of Sex &amp; Marital Therapy</i> <u>25</u> (3):175-192.

Applicants would appreciate the Examiner's initialing and returning attached Forms PTO-1449 to indicate that the cited references therein have been reviewed and made of record.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As applicants are filing this Information Disclosure Statement concurrently with the application, no fee is required.

Respectfully submitted,

7/27/01  
Date

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